NEWCLIP
TECHNICS

K100944

OCT 2 2 2010

510 (k) Summary for the Newclip Clavicle Locking Plating System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following 510(k) summary is submitted for the Newclip Clavicle Locking Plating System.

Summary preparation date: September 15, 2010

1. Submitter:

NEWCLIP TECHNICS
Z.A du Pâtis
Rue de la Fontaine Grillée
F-44 690 La Haye-Fouassière - France
Telephone: (33) 2 28 21 37 12

Contact Person:

J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. Trade name: Newclip Clavicle Locking Plating System

Common Name: Medial Clavicle Plates and screws
Lateral Clavicle Plates and screws

Classification Name: Plate, Fixation, Bone
(21 CFR part. 888.3030)
Screw, Fixation, Bone
(21 CFR part. 888.3040)

3. Predicate or legally marketed devices which are substantially equivalent:

- The Locking Clavicle Plates System of the Congruent Bone Plate System of Acumed, Inc. (K012655),
- The Clavicle Locking Plates of the Peri-Loc Periarticular Locked Plating System for the Upper Extremity of Smith & Nephew; Inc. (K061352),
- The 3.5mm LCP Clavicle Plate System of Synthes (K073186),
- The Claviculaplate with Angular Stability System of I.T.S. Implantat-Technologie-Systeme GmbH (K050852).

NEWCLIP
TECHNICS

4. Description of the device:

The Clavicle Locking Plating System consists of a range of plates and screws for clavicle surgery. Each device is manufactured from titanium and color anodized. The Clavicle Locking Plating System will be provided non-sterile for steam sterilization by health care professional's prior use.

Materials:

Titanium alloy Ti-6Al-4V ELI (conform to ASTM F 136-02a and/or ISO 5832-3).

Function:

The implants of the Clavicle Locking Plating System are indicated for fixation of fractures, mal-unions, non-unions, and osteotomies of the clavicle.

5. Substantial equivalence claimed to predicate devices:

The Clavicle Locking Plating System is substantially equivalent to the Locking Clavicle Plates System of the Congruent Bone Plate System of Acumed, Inc. (K012655), the Clavicle Locking Plates of the Peri-Loc Periarticular Locked Plating System for the Upper Extremity of Smith & Nephew; Inc. (K061352), the 3.5mm LCP Clavicle Plate System of Synthes (K073186) and the Claviculaplate with Angular Stability System of I.T.S. Implantat-Technologie-Systeme GmbH (K050852) in terms of intended use, design, materials used, mechanical safety and performance.

NEWCLIP TECHNICS

The table below compares the features and characteristics of the Newclip Clavicle Locking Plating System to these predicate devices:

Sponsor	NEWCLIP TECHNICS S.A.S.	I.T.S.	ACUMED, INC.	SYNTHES	SMITH & NEPHEW, INC.
Device Name	**Newclip Clavicle Locking Plating System**	**Claviculaplate with Angular Stability System**	**Congruent Bone Plate System** Clavicle Locking Plates	**3.5 mm LCP Clavicle Plate System**	**Peri-Loc Periarticular Locked Plating System** Clavicle Locking Plates
510(K) Number	**K100994**	**K050852**	**K012655**	**K073186**	**K061352**
Regulatory Class	II	II	II	II	II
Device Classification Name	Plate, Fixation, Bone	Plate, Fixation, Bone	Plate, Fixation, Bone	Plate, Fixation, Bone	Plate, Fixation, Bone
Product Code	HRS	HRS	HRS	HRS	HRS
Panel Code	888.3030	888.3030	888.3030	888.3030	888.3030
Intended use					
Indications for Use	Fixation of fractures, mal-unions, non-unions, and osteotomies of the clavicle.	Metaphysial and diaphyseal fracture fixation of acute fractures, malunions, and non-unions of the clavicle. Corrective osteotomy and open and closed fractures.	Fixation for fractures, fusions, or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula.	Fixation of fractures, mal-unions, non-unions, and osteotomies of the clavicle.	Fixation of pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvic, acetabulum, metacarpal, humerus, ulna, radius, calcaneus and clavicle.
Plates design					
o **Design**	Anatomic contour Pre-contoured	Anatomic contour Pre-contoured	Anatomic contour Pre-contoured	Anatomic contour Pre-contoured	Anatomic contour Pre-contoured
Devices					
o **Midshaft Clavicle plates**	Yes	Yes	Yes	Yes	Yes
o **Distal Clavicle plates**	Yes	Yes	Yes	Yes	Yes
o **Fixation system**	Combination of locking and non-locking screws	Combination of locking and non-locking screws	Combination of locking and non-locking screws	Combination of locking and non-locking screws	Combination of locking and non-locking screws
Materials					
o **Plates**	Titanium	Titanium	Titanium	Titanium or stainless steel	Stainless steel
o **Screws**	Titanium	Titanium	Titanium	Titanium or stainless steel	Stainless steel
o **Anodization**	Yes	No	Yes	Yes	No

NEWCLIP
TECHNICS

6. Intended use:

The implants of the Newclip Clavicle Locking Plating System are indicated for fixation of fractures, mal-unions, non-unions, and osteotomies of the clavicle.

7. Non-clinical Test Summary:

The following tests were conducted:

- Comparative bending test on Clavicle plates according ASTM F 382-99 Annex A1.
- Comparative fatigue test on Lateral Clavicle plates according ASTM F 382 – 99 – Annex A2.
- Comparative torsional test on each type of screws according ASTM F543-07 Annex A1.
- Comparative mechanical pullout test on each type of screws according to ASTM F543-07 Annex A3.

8. Non-clinical Test Summary:

No clinical studies were performed.

9. Conclusions Nonclinical and Clinical:

The Newclip Clavicle Locking Plating System is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Newclip Technics
% The Orthomedix Group, Inc.
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

OCT 2 2 2010

Re: K100944
Trade/Device Name: Clavicle Locking Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: September 29, 2010
Received: October 4, 2010

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Bree MD

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NEWCLIP TECHNICS

K100944

OCT 2 2 2010

INDICATIONS FOR USE

510(k) Number (if known): K100944

Device Name: Clavicle Locking Plating System

Indications for Use:

The implants of the Clavicle Locking Plating System are indicated for fixation of fractures, mal-unions, non-unions, and osteotomies of the clavicle.

Prescription Use ✓ AND/OR Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K100944